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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,684	03/01/2002	Shlomit R. Edinger	21402-214 CIP (Cura-514	6438

7590 12/16/2004

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EXAMINER	
SNEDDEN, SHERIDAN	
ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/087,684	EDINGER ET AL.	
	Examiner	Art Unit	
	Sheridan K Snedden	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-10,12-14,19-21,39,42,50 and 51* is/are pending in the application.

4a) Of the above claim(s) *19-21 and 50-51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-10,12-14,39 and 42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/7/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's cancellation of claims 1-4, 11, 15-18, 22-38, 40-41, 43-49 and addition of new claims 50-51 in paper filed 10/26/2004 is acknowledged. Applicant's amendment of claims 5-10, 12, 39 and 42 is also acknowledged. Claims 5-10, 12-14, 19-21, 39, 42, and 50-51 are pending.

2. Applicant's election of invention XX, claims 5-10, 12-14, 39 and 42 is acknowledged. Claims 19-21 and 50-51 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. (Note: new claims 50-51 belong to Group CLVII).

Election was made **with** traverse in Paper filed 10/26/2004. Applicant argues that the elected nucleic acid and a method of determining the presence of the nucleic acid are not distinct because by detecting the nucleic acid the method of Group LV becomes part of the same invention. This argument has been considered but is deemed unpersuasive. Careful inspection of the method of detection indicates that Group LV is directed to a method of using probes capable of hybridizing to the nucleic acid of SEQ ID NO: 3. The presence of the nucleic acid is not required, thus the method is neither a method of using or method of making the nucleic acid. The restriction is proper and made FINAL.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 5-10, 12-14, 39 and 42 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. The above claims are directed to the nucleic acid of SEQ ID NO: 3 encoding protein of SEQ ID NO: 4. The nucleic acid above is disclosed as having utility in treating disease and making the protein of SEQ ID NO: 4, which may also treat disease and may be used in a method of making antibody (see pages 22-23 of specification). Of the above uses, none provide a specific or substantial asserted utility or a well established utility. Basic research, such as studying the properties of the claimed product itself or the mechanisms in which the material is involved, such as gene expression, do not constitute specific or substantial utilities. The therapeutic methods disclosed in the specification teach the treatment of unspecified disease or condition. Where specific diseases are identified, a prophetic use is asserted. Specifically, the specification merely states that the nucleic acids may be provided to subjects in need of NOV1(SEQ ID NO: 3,4) treatment. Neither the specification nor the art of record disclose any diseases or conditions caused or exacerbated by NOV1. The asserted utility in this case essentially is a method of treating an unspecified, undisclosed disease or condition, which does not define a "real world" context of use. Treating an unspecified, undisclosed disease or condition would require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use.

Additionally, the use of the nucleic acid in the method of making a polypeptide that itself has no specific and substantial asserted or well established utility is itself not specific and substantial or well establish. The specification as filed does not disclose or provide any evidence that points to an activity for the protein and furthermore there is no art of record that discloses or suggests any activity for the claimed protein, only potential activity based on homology with

other known proteins. Furthermore, the non-prophetic uses disclosed for the polypeptide, *e.g.* producing antibody, do not show specific utility as it states a general use of all polypeptides.

Thus, the claimed polynucleotide encoding protein is not supported by either a specific and substantial asserted utility or a well established utility as to the above because the specification fails to assert any well established utility for the protein and neither the specification as filed nor any art of record disclose or suggest any activity for the protein such that any utility would be well established for the protein.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 10 is rejected under 35 U.S.C. 102(b) as being anticipated by Carninci *et al.* (Genome Res. 2000 Oct;10(10):1617-30). Carninci *et al.* teach a nucleic acid that comprises 94.92% sequence similarity to the nucleic acid of SEQ ID NO: 3 (see attached sequence alignment). The nucleic acid molecule of Carninci *et al.* would hybridize to SEQ ID NO: 3 under stringent conditions. Thus, the reference clearly anticipates the invention as recited in the claims.

Conclusion

5. No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (571) 272-0959. The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for regular communications to the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SKS
December 1, 2004

JON WEBER
SUPERVISORY PATENT EXAMINER